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| 10/687,289 | 10/15/2003 | Ivan Osorio | 011738.00141 | 8969 |
| 70/467 7590 06/09/2009 BANNER & WITCOFF, LTD AND ATTORNEYS FOR CLIENT NUMBER 011738 10 SOUTH WACKER DRIVE SUITE 3000 CHICAGO, IL 60606 | | | EXAMINER ALTER, ALESSA MARGO | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/687,289

Applicant(s)

OSORIO ET AL.

Examiner

Alyssa M. Alter

Art Unit

3762

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 16-37, 39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 16-37, 39-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB08)
- Paper No(s)/Mail Date 2/26/09 and 3/23/09
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments filed March 23, 2009 have been fully considered but they are not persuasive.

The Applicant argues that Whitehurst fails to disclose an external component that "does not provide a therapy mode". The Applicant further claims that Whitehurst "does not provide the separate feature of providing a therapy treatment mode. However the claims merely recite the limitation that the external component provides "a second treatment therapy mode in accordance with the data, wherein the second treatment therapy mode corresponds to a closed-loop control mode". Therefore, since Whitehurst does employ the external component in a closed-loop mode, and the Applicant considered the "second treatment therapy mode corresponds to a closed-loop control mode", Whitehurst necessarily provides a therapy treatment mode.

Additionally, the Applicant argues that "the external component is not the method for which the treatment therapy is provided and there the external component does not provide the treatment therapy". In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the external component administering the therapy) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Furthermore, since the external component modifies the therapy, the external component does provide the medical system with modified therapy.

Additionally, the Applicant argues a switching feature. However, as previously stated, Whitehurst does in fact automatically switch between modes, specifically open and closed loop mode. However, Whitehurst discloses on page 8, paragraph 92, "external electronic appliance 230 may include an automatic algorithm that adjusts electrical and/or drug stimulation parameters automatically whenever the SCU(s) 130 is/are recharged". Therefore, Whitehurst discloses that during charging the system can automatically convert from a closed-loop operation to an open-loop operation and accept modifications or adjustments from the external component.

Alternatively, the examiner maintains that it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate an automatic mode of switching between open and closed loop operations in order to enable switching between physician programming and self-reliant operation in order provide the predictable results of modifying the therapy treatment to meet specific patient needs and requirements by updating and modifying the operation parameters. Also such an automatic mode switch would permit power conservation for the system by only enabling the implanted medical device to employ the telemetry transmission when there is communication that is detected.

Therefore the claims remain rejected in view of Whitehurst (US Patent Publications 20020013612 A1).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims 1 and 11 are vague. The implantable device has not been set forth to operate in a closed-loop mode only the external device.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-13, 16-19, 21-29, 32, 35-37 and 39-40 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious

over Whitehurst (US Patent Publications 20020013612 A1). Whitehurst discloses a system and method for treating mood or anxiety disorders, which is a nervous system disorder, by stimulating the brain utilizing an implantable system control unit (SCU), electrodes and a pulse generator for treatment.

As to claims 1, 4, 11, 13, 19 and 39, the system is capable of open- and closed-loop operation. Open loop operation does not require feedback, while closed loop operation does utilize feedback. Feedback, in order to modify the monitoring and programming capabilities of the SCU, can be provided by a sensor, patient or clinician. In the event that the feedback is transmitted to a SCU by a patient or clinician through an external component, hand help patient programmer (HHP) 190 or clinician through a clinician programming system (CPS) 192, the external component is modifying the treatment mode and thus creating a closed loop operation. This closed loop treatment operation is considered to be the second treatment mode and as such the second treatment therapy mode corresponds to a closed-loop control mode. When the external component modifies the function of the SCU, the external component is "coupled" to the SCU via telemetry or the first communications channel. In the event that the external component is not sending telemetric signals, the external component is not actively "coupled" to the SCU, and is thus functioning in the open loop operation, which is considered to be the first treatment mode. Therefore, the first treatment therapy mode corresponds to an open-loop control mode.

Furthermore, as to claims 1, 4, 11, 13, 19, 21-22, 28, 35-36 and 39, Whitehurst discloses on page 7, paragraph 84, "when it is required to communicate with SCU 130,

patient 200 is positioned on or near external appliance 220, which appliance contains one or more inductive coils 222 or other means of communication (e.g., RF transmitter and receiver)". Therefore, the SCU is selectively "coupled" in a closed-loop operation or uncoupled away from the external components in an open-loop operation.

Still further, Whitehurst discloses on page 8, paragraph 92, "external electronic appliance 230 may include an automatic algorithm that adjusts electrical and/or drug stimulation parameters automatically whenever the SCU(s) 130 is/are recharged". Therefore, Whitehurst discloses that during charging the system can automatically convert from a closed-loop operation to an open-loop operation and accept modifications or adjustments from the external component.

Additionally, Whitehurst discloses on page 8, paragraph 90, "it may alternatively **or additionally** be desirable to use a separate or specialized implantable device to record and telemeter physiological conditions/responses in order to adjust electrical stimulation and/or drug infusion parameters. This information may be transmitted to an external device, such as external appliance 220, or may be transmitted directly to implanted SCU(s) 130". Therefore, since there are two modes of operation, closed loop and open loop, there would necessarily be an automatic mode of switching between but the open-loop and closed-loop modes.

In the alternative, although the examiner considers Whitehurst to disclose a switching mode above, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate an automatic mode of switching between open and closed loop operations in order to enable switching between

physician programming and self-reliant operation in order provide the predictable results of modifying the therapy treatment to meet specific patient needs and requirements by updating and modifying the operation parameters. Also such an automatic mode switch would permit power conservation for the system by only enabling the implanted medical device to employ the telemetry transmission when there is communication that is detected.

As to claims 2-3 and 5, the programmers the examiner considers the MDS 194 to be the programmer that is in direct communication with the SCU(s) and the CPS to be a programmer in indirect communication with the SCU(s) as discloses on page 7, paragraph 82. Additionally the HHP 190 functions as a relay module. Additionally, the third treatment mode is the administering of drug stimulation.

As to claims 6, Whitehurst discloses on page 8, paragraph 90, "it may alternatively or additionally be desirable to use a separate or specialized implantable device to record and telemeter physiological conditions/responses". Thus Whitehurst inherently contains a memory configured to store data.

As to claims 24-25, as seen in figure 6, the system is a hybrid system with implanted system components and external system components.

As to claims 7 and 26-27, the sensing function or device for the sensing symptoms or other prognostic or diagnostic indicators of mood and/or anxiety disorders is the triggering device that affects at least one of the treatment therapy modes.

As to claims 8, the second communications channel is 246 as displayed in figure 7 between the first external appliance 230 and the other computing means 248.

As to claims 9-10, 12, 23 and 32, the examiner considers the additional module or external component to be the clinician programming device CPS 192, which is capable of communicating with the SCU via the HHP 190. The CPS 192 can also support an additional treatment therapy, such as the administration of drug stimulation.

As to claims 16 and 37, the first treatment therapy mode is an open-loop mode, which is equivalent to basic loop recording, and the second treatment therapy mode is a closed-loop mode, which is equivalent to enhanced loop recording.

As to claim 17-18, Whitehurst discloses a system and method for treating mood or anxiety disorders, which is a nervous system disorder, by utilizing an implantable system control unit (SCU), electrodes and a pulse generator for treatment.

2. Claims 30-31 and 33 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Whitehurst (US Patent Publications 20020013612 A1). Whitehurst discloses on page 9, paragraph 106, "the electrical and/or drug stimulation parameters are adjusted in a closed-loop manner to provide stimulation tailored to the need for and/or response to the electrical and/or drug stimulation". Since the second treatment mode corresponded to the closed loop treatment, Whitehurst necessarily provides incremental treatment for the second treatment mode in order to adjust and tailor the SCUs functions.

In the alternative, although the examiner considers Whitehurst to disclose incremental treatment therapy for the second treatment mode, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incrementally adjust the parameters of the SCUs in order to provide the predictable

results of refining treatment and not expose the patient to drastic variations or differences in the treatment parameters.

3. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehurst (US Patent Publications 20020013612 A1). Whitehurst discloses the claimed invention except for the alarm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the second treatment therapy mode to include an alarm since it is known in the art to notify patients with an alarm system of impending stimulation or treatment. Furthermore, such an alarm or notification system would provide the predictable results of notifying the patient of detected precursors to a medical condition, such as seizure or cardiac condition, and imminent treatment.

4. Claim 20 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehurst (US Patent Publications 20020013612 A1) in view of Haller et al. (US Patent Publication 20020013613 A1) for reasons previously made of record. Whitehurst discloses the claimed invention except for the sensing of the patient location. Haller et al. teaches that it is known to use a GPS system to identify the location of the patient, for the purpose of monitoring the patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the therapy system as taught by Whitehurst with the GPS system as taught by Haller et al., in order to monitor and provide assistance to the patient in the event the patient is incapacitated and cannot request help.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alyssa M Alter/
Examiner
Art Unit 3762